510(K) SUMMARY

DEC 14 2012

General Information

Manufacturer:	Gyrus ACMI 6845 Wedgewood Rd. Maple Grove, MN 55311 ERN: 3005975494
510(k) Submitter:	Gyrus ACMI 136 Turnpike Rd. Southborough, MA 01772-2104 ERN: 3003790304
Contact Person:	Neil Kelly (508) 804-2690 neil.kelly@Olympus-OSTA.com
Date Prepared:	October 26, 2012
Classification Name:	Unit, Electrosurgical, Endoscopic (With or Without Accessories) Gastroenterology/Urology KNS 21 CFR 8876.4300 Class II
Trade Name:	BiCOAG Hemostasis Probe
Generic/Common Name:	BiCOAG, BiCOAG Probe

Predicate Device

Gyrus ACMI BiCOAG Hemostasis Probe K092571

Indications for Use

The Gyrus ACMI BiCOAG Hemostasis Probe is intended for coagulation of active bleeding lesions in the upper or lower gastrointestinal tract during endoscopic procedures.

Product Description

The BiCOAG Hemostasis Probe is a single use disposable high frequency RF accessory to be used in conjunction with a generator with bipolar frequency energy rated up to 500Vp-p. The BiCOAG Hemostasis Probe is intended to be used for coagulation of active bleeding lesions in the upper or lower gastrointestinal tract. It contains a central irrigation port. The probe is to be available in 10 Fr and 7 Fr (3.3mm and 2.3mm respectively) outer diameter configurations to allow its use through a minimum 3.7mm and 2.8mm endoscope working channel, respectively. The device is intended to be passed through the working channel of an endoscope to provide hemostasis throughout the gastrointestinal tract.

The BiCOAG Hemostasis Probe enables irrigating fluid (sterile water) to be delivered at the electrode tip. This fluid enables the clearing of blood and other substances that often impede vision and coagulation of the surgical site.

The probe is bipolar with electrodes that spiral down the tip in a uniform manner. These electrodes carry desiccating RF current to a site where bleeding is occurring and allows for coagulation at the target site. The hole at the end of the probe allows for irrigating water to clean the surgical site as required when used in conjunction with a bipolar generator and endoscope. The system thus provides endoscopic control and hemostasis of upper and lower GI bleeding by the application of bipolar energy.

Proposed to Predicate Comparison

Change	Predicate Device K092571 (From)	Proposed Device (To)	Reason
Conductive Trace Material	Nickel-plated Palladium	Gold	Improves manufacturability. New material found to be biocompatible, and performed substantially equivalent to the predicate material. (Material)
Tip to Wire Electrical Joint	Tin-lead solder	Conductive epoxy	Improves manufacturability of electrical joint with gold trace material and proposed conductive epoxy is RoHS compliant. (Material, Component)
Wire to Power Cord Electrical Joint	Tin-lead solder	Tin-silver solder	Proposed solder is intended for electrical applications and is RoHS compliant. (Material)
10Fr Tip Material	Machined alumina	Molded zirconia	Higher mechanical strength and improves manufacturability. Material already in use on the 7Fr predicate device. (Material)
Bifurcation Joint	Overmolded	Two-piece Assembly (potting cup and lid)	Improves reliability and resistance to leaks with improved flow. (Component)
Coaxial Plug	Manufactured	Purchased	Coaxial plug is an industry standard design and was readily available from an existing vendor. Removes steps from current manufacturing process. (Component)
Luer Adhesive Change	UV-cure adhesive	UV-cure adhesive with tint	Original adhesive has become obsolete by the vendor. New adhesive performs substantially equivalent to the original but changes color from blue to clear when cured which aids in assembly. (Material)
Tip to Body Stock Adhesive Change	Moisture-cure adhesive	Epoxy	Improved manufacturability and epoxy is RoHS compliant. (Material, Component)

These device modifications have been tested against the predicate device and are found to perform substantially equivalent. No new issues of safety or effectiveness are raised by these changes.

Performance Data, Technological features, and Substantial Equivalence

The Gyrus ACMI BiCOAG Hemostasis Probe, as described in this submission, is substantially equivalent to the predicates in intended use, principles of operation, performance, and fundamental scientific technology.

Design verification testing was carried out on the bench to ensure the performance and reliability of the proposed device all with passing results. Testing such as physical dimensions, flow rates, pull testing, leak testing, performance, electrical, packaging, shelf life, sterilization, and Biocompatibility were all carried out and met acceptance criteria. In addition, a non-clinical bench study was carried out by a trained user on porcine tissue to evaluate the coagulation of the proposed probe against the predicate, and a few other market competitors. All specifications of the BiCOAG Hemostasis Probe that required verification and/or validation to ensure the proposed device is substantially equivalent to the predicate BiCOAG Hemostasis Probe have successfully achieved the acceptance criteria and raised no new issues of safety or effectiveness.

Summary

The proposed Gyrus ACMI BiCOAG Hemostasis Probe, as described in this submission, raises no new issues of safety or effectiveness as compared to the predicate device and has been found substantially equivalent to the currently marketed predicate Gyrus ACMI BiCOAG Hemostasis Probe.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Olympus Surgical Technologies America
% Mr. Neil Kelly
Regulatory Affairs Specialist
136 Turnpike Road
Southborough, Massachusetts 01772

December 14, 2012

Re: K123319
Trade/Device Name: Gyrus ACMI® BiCOAG Hemostatis Probe
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic electrosurgical unit and accessories
Regulatory Class: Class II
Product Code: KNS
Dated: November 21, 2012
Received: November 21, 2012

Dear Mr. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K123319

Device Name: Gyrus ACMI® BiCOAG Hemostasis Probe

Indications for Use:

The Gyrus ACMI BiCOAG Hemostasis Probe is intended for coagulation of active bleeding lesions in the upper or lower gastrointestinal tract during endoscopic procedures.

Prescription Use: _X_ OR Over-the-Counter Use: ___

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwight Yen
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(Division Sign-Off)

Division of Surgical Devices

510(k) Number K123319